A REGISTRY TO COLLECT CHARACTERISTICS AND OUTCOMES FROM PATIENTS WITH SOLID TUMORS PROFILED WITH A NEXT-GENERATION SEQUENCING TEST (WAYFIND-R)

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Main Information

Primary registry identifying number
LBCTR2022105085

Protocol number
MX39897

MOH registration number

Study registered at the country of origin
No

Study registered at the country of origin: Specify
Not Applicable - The Registry will be conducted in several countries worldwide including EU countries like France

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
27/08/2020

Primary sponsor
F. Hoffmann-La Roche Ltd

Primary sponsor: Country of origin
Switzerland

Date of registration in primary registry
24/10/2022

Date of registration in national regulatory agency
27/08/2020

Public title
A REGISTRY TO COLLECT CHARACTERISTICS AND OUTCOMES FROM PATIENTS WITH SOLID TUMORS PROFILED WITH A NEXT-GENERATION SEQUENCING TEST (WAYFIND-R)

Acronym
WAYFIND-R

Scientific title
A REGISTRY TO COLLECT CHARACTERISTICS AND OUTCOMES FROM PATIENTS WITH SOLID TUMORS PROFILED WITH A NEXT-GENERATION SEQUENCING TEST (WAYFIND-R)

Acronym
WAYFIND-R

Brief summary of the study: English

This is an observational, non-interventional, prospective, multinational and multicenter solid tumor cancers registry. Patients with any type of malignant solid tumor will be targeted for enrolment. Patients who have undergone NGS testing no more than 3 months prior to the enrolment date will be included, irrespective of the availability of test results. All medicinal products used to treat solid tumor cancers (all oncology treatments) are considered studied medicinal products for this registry.

The study has several objectives, the most prominent of which are:
-To provide a platform to support the design and conduct of clinical and epidemiological research
-To develop an evidence-generation platform to better understand health outcomes and cancer care processes
-To characterize the treatments and clinical course of solid tumor cancers in patients who have undergone NGS testing

Participants' data will be abstracted from the medical records collected by the registry treating physician or medical staff and recorded on electronic case report forms (eCRFs). Data from participant medical records and notes should be entered on the eCRFs as soon as they become available, or at regular intervals and for all visits that occurred within every 6 months from the enrolment or previous visit until participant withdrawal or discontinuation of the site or the
registry, whichever occurs first. Data on pregnancy should be reported using the paper pregnancy reporting form provided by the Sponsor.
Additionally, at the time of the patient's enrolment visit two baseline information forms will be
collected:
-A baseline physician information form on rationale/reason for ordering NGS testing and the reimbursement for the test (for each patient enrolled in the registry)
-A baseline patient information form to collect, risk factors, confounders and effect modifiers including comorbidities and sociodemographic information that may not be present or well completed in patient medical records

Due to the nature of this registry, it is currently not possible to determine the exact sample size; however, we aim to enroll around ≥15,000 patients by 2026 and beyond based on enrolment rate.

Brief summary of the study: Arabic

هذه الدراسة هي عبارة عن دراسة تسجيل رصدية غير تدخلية استطلاعية متعددة الجنسيات ومتعددة المراكز على الأورام السرطانية الصلبة.
سيتم استهداف المرضى ممن يعانون من أي نوع من الأورام الصلبة الخبيثة. سيتم تضمين المرضى الذين خضعوا لاختبار تسلسل الجيل التَّالي أشهر من تاريخ التسجيل، بصرف النظر عن توفر نتائج الاختبار. تعتبر جميع المنتجات الدوائية المستخدمة لعلاج الأورام3قبل ما لا يزيد عن السرطانية الصلبة (جميع علاجات الأورام) منتجات طبية خاضعة للدراسة في دراسة التسجيل.
للدراسة عدة أهداف، أبرز عناوينها هي:
-توفير منصة لدعم تصميم وإجراء البحوث السريرية والوبائية
-استحداث منصة لتوليد الأدلة لفهم النتائج الصحية وعمليات رعاية مرضى السرطان بشكل أفضل
-توصيف العلاجات والمسار السريري للأورام السرطانية الصلبة في المرضى الذين خضعوا لاختبار تسلسل الجيل التَّالي

سيتم استخراج بيانات المشاركين من السجلات الطبية التي جمعها الطبيب المعالج أو الطاقم الطبي بدراسة التسجيل والمسجلة في نماذج تقرير الحالة الإلكترونية (eCRFs). يجب إدخال البيانات المأخوذة من السجلات الطبية والملاحظات الخاصة بالمشاركين في نماذج تقرير الحالة أشهر من وقت التسجيل أو الزيارة السابقة حتى6الإلكترونية بمجرد توفرها، أو على فترات منتظمة ولجميع الزيارات التي حدثت خلال كل انسحاب المشارك أو توقف الموقع أو دراسة التسجيل، أيهم يحدث أولا. يجب الإبلاغ عن البيانات المتعلقة بالحمل باستخدام النموذج الورقي للإبلاغ عن الحمل المُقدَّم من الشركة الرَّاعية.
بالإضافة إلى ذلك، في وقت زيارة تسجيل المريض، سيتم جمع نموذجي المعلومات الخاصين ببدء الدراسة:
-نموذج معلومات الطبيب عند بدء الدراسة حول الأساس المنطقي/سبب طلب اختبار تسلسل الجيل التَّالي وسداد تكاليف الاختبار (لكل مريض مسجل في دراسة التسجيل)
-نموذج معلومات المريض الخاص ببدء الدراسة لجمع عوامل الخطورة والعوامل المربكة ومُحَوِّرَات التأثير ومن ضمنها الأمراض المصاحبة والمعلومات الاجتماعية الديموجرافية التي قد لا تكون موجودة أو مكتملة بشكل جيد في السجلات الطبية للمريض

2026 مريض بحلول عام 15000نظرًا لطبيعة دراسة التسجيل هذه، لا يمكن حاليًّا تحديد حجم العينة بدقة؛ ومع ذلك، نهدف إلى تسجيل نحو ≤ وما بعده بناءً على معدل التسجيل.

Health conditions/problem studied: Specify

The registry population will include adult patients who are diagnosed with solid tumor cancers (at any anatomical location) and at any stage of the disease.

Interventions: Specify

Non-interventional study

Key inclusion and exclusion criteria: Inclusion criteria

Patients must meet the following criteria for enrolment in this registry:
- Patient is an adult (according to age of majority as defined by local regulations)
- Patient is currently diagnosed with any type of solid tumor cancer, at any stage of the disease, at the enrolment date (informed consent date)
- Patient has undergone NGS testing, no longer than 3 months prior to the enrolment date, irrespective of the availability of test results
- Informed consent has been obtained from the patient or legally authorized representative, as per local regulations

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

Patients who meet the below exclusion criterion at the time of enrolment will not be enrolled in this registry:
- Patient has a prior or current diagnosis of hematological malignancy

Type of study

Observational

Type of intervention

N/A

Type of intervention: Specify type

N/A

Trial scope

N/A

Trial scope: Specify scope

N/A

Study design: Allocation

N/A

Study design: Masking

N/A

Study design: Control

N/A

Study phase

N/A

Study design: Purpose

N/A

Study design: Specify purpose

N/A

Study design: Assignment

N/A

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Therapeutic indication

Therapeutic benefit

Study model

Study model: Explain model

Other

Study model: Specify model

Registry

This is an observational, non-interventional, prospective, multinational and multicenter solid tumor cancers registry. As per the EMA discussion paper, a patient registry is an organized data collection system that uses observational methods to collect uniform data on a patient population that is followed over time (EMA 2018). Patients enrolled in this registry might be already enrolled in a clinical trial or might be offered participation in a clinical trial at the same time, as applicable per inclusion/exclusion criteria of the clinical trial.

This registry will not be a product registry, as it aims to collect data on patients who are undergoing a variety of treatments for diverse solid tumors that are not predefined. Instead, enrolment is subject to the prescription of NGS within clinical practice, irrespective of the availability of test results.

Time perspective

Prospective

Time perspective: Explain time perspective

Observation Period for the participant:
The term “observation period” is defined as the period spanning from the date of consent until the date of death, loss to follow-up, withdrawal of consent, registry closure by Sponsor or site withdrawal from the registry, whichever occurs first.

Time perspective: Specify perspective

N/A

Target follow-up duration

2

Target follow-up duration: Unit

years

Number of groups/cohorts

1

Biospecimen retention

None retained

Biospecimen description

NA

Target sample size

15000

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

15/11/2022

Date of study closure: Type

Anticipated

Date of study closure: Date

31/12/2024

Recruitment status

Pending

Recruitment status: Specify

Date of completion

31/12/2024

IPD sharing statement plan

Yes

IPD sharing statement description

The Sponsor maintains confidentiality standards by coding each participant enrolled in the registry through assignment of a unique participant identification number. This means that participant names or other direct identifiers are not included in datasets that are transmitted to any Sponsor location. Data protection and privacy regulations will be followed in capturing, processing, storing and sharing participant data, in accordance with local applicable privacy and confidentiality requirements. An external anonymized data sharing plan that aligns with national regulations and EU GDPR (2016) (General Data Protection Regulation) will be developed. This will outline the mechanism of data sharing with relevant research parties who are interested in utilizing the data collected in this registry for conducting SDU studies. The data will be stored in a data warehouse after closing the registry. Participant medical information obtained by this registry is confidential and may be disclosed to third parties only as permitted by the ICF (or separate authorization for use and disclosure of personal health information) signed by the participant, unless permitted or required by law. Medical information may be given to a participant's personal treating physician or other appropriate medical personnel responsible for the subject's welfare, for treatment purposes.
Data collected by this registry must be available for inspection upon request by representatives of national and local health authorities, Sponsor monitors, representatives, collaborators and the IRB/EC for each registry site, as appropriate.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

No Numbers

Sources of Monetary or Material Support

Name
F. HOFFMANN-LA ROCHE LTD

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Hampig Kourie	Hotel Dieu De France - ALFRED NACCACHE STREET 20631111 Beirut	Lebanon	01604000	hampig.kourie@hotmail.com	Hotel Dieu De France
Scientific	Hampig Kourie	Hotel Dieu De France - ALFRED NACCACHE STREET 20631111 Beirut	Lebanon	01604000	hampig.kourie@hotmail.com	Hotel Dieu De France

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Dr. Hamig Kourie	Hematologist-Oncologist & Oncogeneticist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	31/05/2022	Professor Sami Richa	cue@usj.edu.lb	+961-1-421 229

Countries of Recruitment

Name
Lebanon
Argentina
Austria
Brazil
Canada
Colombia
France
Greece
Hungary
Ireland
Mexico

Portugal
Spain
Thailand
Turkey
United Kingdom
Germany
Estonia
Philippines
Republic of Serbia
Slovenia
Viet Nam
Taiwan
Chile
Slovakia
India
South Africa
Poland
Egypt
United Arab Emirates
Saudi Arabia

Health Conditions or Problems Studied

Condition	Code	Keyword
Solid Tumors	Neoplasm of uncertain or unknown behaviour, unspecified (D48.9)	ALL SOLID TUMORS

Interventions

Intervention	Description	Keyword
Non-Interventional Study (Registry)	NA	NA

Primary Outcomes

Name	Time Points	Measure
To provide a platform to support the design and conduct of clinical and epidemiological research	NA being that it's a registry	- Collect data that can inform future trial design and facilitate identification of potential trial populations - Provide a resource to identify, develop and qualify biomarkers, novel assessment tools and clinical endpoints - Provide a resource to support the conduct of disease-modeling studies
To develop an evidence-generation platform to better understand health outcomes and cancer care processes	NA being that it's a registry	- Provide a resource to inform how precision medicine tools are used and how they affect patient care in the real world - Provide a resource to generate evidence that can support clinical, regulatory and access decision-making - Provide a resource to identify and assess clinical practices that can improve the healthcare of affected individuals
To characterize the treatments and clinical course of solid tumor cancers in patients who have undergone NGS testing	NA being that it's a registry	- Collect data that describes the history of patients undergoing NGS testing - Collect data that can help identify the complex genomic landscape affecting the diagnosis and prognosis of solid tumor cancers and deepen the understanding of underlying biologic pathways - Collect data that can help identify sub-populations that may best benefit from precision medicine tools

Key Secondary Outcomes

Name	Time Points	Measure
NA - It's a registry	NA	NA

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files